DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed December 15, 2011 is acknowledged and has been entered. Claims 1-39 and 45-53 have been canceled. Claims 40-44 and 54-56 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments, however a new ground of rejection is set forth below.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 40-44 and 54-56 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 23 of U.S. Patent No. 7935675 in view of Krieg et al (7723500). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim and disclose methods of administering a composition comprising an antigen (i.e. vaccine) and immunostimulatory oligonucleotide (i.e. adjuvant) and a delivery complex. Claim 23 of 7935675 is directed to the method of claim 1, wherein the nucleic acid is delivered in a formulation selected from the group consisting of a nucleic acid delivery complex, a liposome, a virosome, and a nanoparticle. With regard to the limitation of immunostimulatory oligonucleotides having greater than two unmethylated cytosine-guanine dinucleotides, it is noted that both patents, 7935675 and 7723500, disclose immunostimulatory oligonucleotides having greater than two unmethylated cytosine-guanine dinucleotides (for 7935675, see SEQ ID NO: 56, 75, 80, 82, 84, 120, 123; for 7723500, see SEQ ID NO: 5, 18-21). A "nucleic acid delivery complex" shall mean a nucleic acid molecule associated with (e.g., ionically or covalently bound to; or encapsulated within) a targeting means (7935675, description paragraph 44). The 7723500 patent both claims and discloses that a delivery complex is a cationic lipid; the patent also claims and discloses the use of antigens in the composition that is to be administered. 7732500 (at [0060]; see also claims) disclose “A "nucleic acid delivery complex" shall mean a nucleic acid molecule associated with (e.g. ionically or covalently bound to; or encapsulated within) a targeting means (e.g. a molecule that results in higher affinity binding to target cell (e.g. B-cell and natural killer (NK) cell) surfaces and/or increased cellular uptake by target cells). Examples of nucleic acid delivery complexes include nucleic acids associated with: a sterol (e.g. cholesterol), a lipid (e.g. a cationic lipid, virosome or liposome), or a target cell specific binding agent (e.g. a ligand recognized by target cell specific receptor).” 7723500 also claims that the composition comprises an antigen, and discloses that “[0021] In a second aspect, the invention features useful therapies, which are based on the immunostimulatory activity of the nucleic acid molecules. For example, the immunostimulatory nucleic acid molecules can be used to treat, prevent or ameliorate an immune system deficiency (e.g., a tumor or cancer or a viral, fungal, bacterial or parasitic infection in a subject). In addition, immunostimulatory nucleic acid molecules can be administered to stimulate a subject's response to a vaccine.”

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the methods claimed in 7935675 along with the teachings disclosed and claimed in 7723500 with the reasonable expectation of success of a stimulating a subject's response to a vaccine comprising administering a vaccine, immunostimulatory oligonucleotide. Both patents teach use of the composition for the same reasons. The claimed invention is prima facie obvious in view of the art absent any convincing evidence to the contrary.

The rejection is maintained for the reasons of record. Applicant's arguments filed December 15, 2011 have been fully considered but they are not persuasive. Applicants have asserted that the Examiner indicated that there is overlap between the claimed method and the claims of the issued patent. Applicants have also asserted that "Mere overlap is not enough." However, it is the Examiner's position that the previous Office Action made no such statements or assertions. The claims are obvious (and unpatentable) over claims 1 and 23 of U.S. Patent No. 7935675 in view of Krieg et al (7723500). It is noted that there is no requirement to use only the claims of the secondary reference, the secondary reference could be non-patent literature. Therefore the four corners of the secondary reference can be used.

Applicants have asserted that issued patent (7935675) claims a method of treating asthma by administering a CpG oligonucleotide and a delivery complex and that the claims do not recite the administration of a vaccine; thus the claims of the issued patent are not the same as the claims of the pending application. Applicants have asserted that the pending claims recite substantial and nonobvious limitations when considered in view of the issued claims. Significantly, a method for producing an immune response to a vaccine involves the production of an antigen specific immune response. The fact that a composition of an oligonucleotide in the absence of a vaccine or antigen (the issued claims of the '675 patent are silent) can be used to treat asthma is not sufficient to provide a reason able expectation that such a composition would produce an antigen specific immune response.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Further, with regard to the limitation of "greater than two unmethylated cytosine-guanine dinucleotides", it is noted that the issued patent claims recite "immunostimulatory nucleic acid, having a sequence including at least the following formula: 5'$X_1X_2CGX_3X_4$3'." The oligonucleotides comprise more than the specific formula. The specification of the issued patents was only used to show the full scope of the meaning of this generic phrase. Both patents, 7935675 and 7723500, disclose immunostimulatory oligonucleotides having greater than two unmethylated cytosine-guanine dinucleotides (for 7935675, see SEQ ID NO: 56, 75, 80, 82, 84, 120, 123; for 7723500, see SEQ ID NO: 5, 18-21). The specification can be used as a dictionary to interpret the scope of the claims. It is also noted that the neither the '675 claims nor the instant claims specifically recite a particular oligonucleotide, but merely provides the characteristics of the oligonucleotides. The same is true for the recitation of "delivery complex", issued patent (7935675) claim 23 recites a delivery complex. Both issued patents define the delivery complex in the same manner as the instant claims. Again, the specification can be used as a dictionary to interpret the scope of the claims.

It is the Examiner's position that 7723500 also claims that the composition comprises an antigen, and discloses that "[0021] In a second aspect, the invention features useful therapies, which are based on the immunostimulatory activity of the nucleic acid molecules. For example, the immunostimulatory nucleic acid molecules can be used to treat, prevent or ameliorate an immune system deficiency (e.g., a tumor or cancer or a viral, fungal, bacterial or parasitic infection in a subject). In addition, immunostimulatory nucleic acid molecules can be administered to stimulate a subject's response to a vaccine." This would appear to be the same reasoning or motivation of the instant claims (i.e. stimulating a subject's response to a vaccine). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the methods claimed in 7935675 along with the teachings disclosed and claimed in 7723500 with the reasonable expectation of success of a stimulating a subject's response to a vaccine comprising administering a vaccine, immunostimulatory oligonucleotide linked to a nucleic acid delivery complex. Both patents teach use of the composition for the same reasons. The claimed invention is prima facie obvious in view of the art absent any convincing evidence to the contrary.

4. No claims are allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. MINNIFIELD whose telephone number is (571)272-0860. The examiner can normally be reached on M-F (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. M. MINNIFIELD/
Primary Examiner, Art Unit 1645